Paper No. 18

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JOHN E. SIMS, DAVID J. COSMAN,
STEPHEN D. LUPTON, BRUCE A. MOSLEY, and STEVEN K. DOWER

Appeal No. 1999-1430
Application No. 08/441,893

ON BRIEF

Before, WILLIAM F. SMITH, ADAMS, and MILLS Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 16 and 23-25, which are all the claims pending in the application.

Claim 16[1] is illustrative of the subject matter on appeal and is reproduced below:

16. An isolated and purified Type II IL-1 receptor (Type II IL-1R) that binds IL-1, and is encoded by a DNA that hybridizes under moderately stringent conditions with a DNA selected from the group consisting of:
    (a) a DNA encoding a Type II IL-1R having an amino acid sequence as set forth in SEQ ID NO.:2, having an amino terminus at amino acid 1, and a carboxy terminus selected from the group consisting of an amino acid between amino acids 330 and 385, inclusive, of SEQ ID NO.:2;
    (b) a DNA encoding a Type II IL-1R having an amino acid sequene as set forth in SEQ ID NO.:13, having an amino terminus at amino acid 1, and a carboxy terminus selected from the group consisting of an amino acid between amino acids 342 and 397, inclusive, of SEQ ID NO.:13; and
    (c) a DNA encoding a fragment of the polypeptide of (a) or (b), which fragment binds IL-1.

References relied upon by the examiner[2].

Sims et al. (Sims)	5,464,937	Nov. 7, 1995

[1] We note the examiner's notation (Answer, page 3) of errors present in appellants' Brief, Appendix A, Claims on Appeal. Claim 16 is correctly reproduced herein.
[2] We note the examiner incorrectly states (Answer, page 3) that "[n]o prior art is relied upon by the examiner in the rejection of the claims under appeal."

GROUNDS OF REJECTION[3]

Claims 16 and 23-25 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of Sims.

Claims 16, and 23-25 are rejected under 35 U.S.C. § 112, first paragraph, as based on a non-enabling disclosure.

We affirm the rejection under the judicially created doctrine of obviousness-type double patenting. We vacate[4] the rejection under 35 U.S.C. § 112, first paragraph.

DISCUSSION

Obviousness-type double patenting:

In response to this rejection appellants state (Brief[5], page 13):

> Appellants filed a terminal disclaimer on January 7, 1997. The fee set forth in 37 C.F.R. § 1.20(d) was not paid at the time the [sic]. A copy of the terminal disclaimer and the appropriate fee will be filed upon notice that the Board has reversed the [e]xaminer's rejection of the pending claims under 35 U.S.C. § 112, first paragraph.

[3] We note as does the examiner (Answer, page 3) that the requirements of 37 CFR §§ 1.821-1.825 represent petitionable rather than appealable subject matter. Accordingly, the Board of Patent Appeals and Interferences has no jurisdiction to review appellants' compliance with the rules regarding sequence disclosures. In re Hengehold, 440 F.2d 1395, 1403-1404, 169 USPQ 473, 479-480 (CCPA 1971).

[4] Lest there be any misunderstanding, the term "vacate" in this context means to set aside or to void. When the Board vacates an examiner's rejection, the rejection is set aside and no longer exists.

[5] Paper No. 15, received December 18, 1997.

Appellants provide no further comment with regard to this rejection. Accordingly, we affirm the examiner's rejection of claims 16 and 23-25 under the judicially created doctrine of obviousness-type double patenting.

35 U.S.C. § 112, first paragraph:

According to the examiner (Answer[6], page 4) "the disclosure is enabling only for claims limited to proteins which correspond in scope to those protein[s] which are encoded by the nucleic acid of the allowed claims from U.S. Patent Application Number 08/242,211, now Patent Number 5,464,937." The examiner finds (Answer, page 4) that "the presence of the hybridization limitation of the instant claims has the effect of encompassing any mutant of the disclosed type II IL-1R which retains the ability to bind IL-1.

The examiner reasons (Answer, pages 5-6) that:

> The instant specification does not provide a single working example of an IL-2 [sic] receptor whose amino acid sequence deviates from a natural amino acid sequence and yet the claims encompass potentially thousands of embodiments which do. Further, the instant specification does not identify those amino acid residues in the amino acid sequence of either of the two disclosed type II IL-1 receptors which are essential for their biological activity and structural integrity and those residues which are either expendable or substitutable. In the absence of this information a practitioner would have to resort to a substantial amount of undue experimentation in the form of insertional, deletional and substitutional mutation analysis of over three hundred amino acid residues before they could even begin to rationally design a functional IL-1 receptor having other than a natural amino acid sequence. The disclosure of two DNAs encoding two IL-1 receptors, each having it's natural amino acid sequence, is clearly insufficient support under the first paragraph of 35 U.S.C. § 112 for claims which encompass any and all type II IL-1 receptor proteins, including mutants thereof, which are encoded by a DNA which

[6] Paper No. 16, mailed February 11, 1998.

> hybridizes to any DNA encoding one of the disclosed proteins under moderate or even high stringency conditions.

In response appellants argue (Brief, page 7):

> With respect to the breadth of the claims, contrary to the [e]xaminer's position, the claims do not encompass ANY and all mutants, variants, or derivatives of SEQ ID NO:2 and SEQ ID NO:13. Similarly, the claims do not encompass potentially thousands of embodiments that deviate from the natural amino acid sequences. The claims encompass polypeptides that bind IL-1 and which are encoded by DNA that hybridizes under specified conditions to the DNA that encodes SEQ ID NO:2 or SEQ ID NO:13. [Emphasis removed].

With regard to the quantity of experimentation appellants argue (Brief, page 8) that:

> [T]he [e]xaminer has erroneously maintained that "a practitioner would have to resort to a substantial amount of undue experimentation in the form of insertional, deletional and substitutional mutation analysis …" The CAFC has consistently held that the test is not merely quantitative, because a considerable amount of experimentation is permissible, if it is merely routine. … It is further the law that the disclosure of a large number of embodiments does not render a claim broader than the enabled scope as long as undue experimentation is not involved in determining the embodiments.
>
> …
>
> There is simply no room to conclude that the quantity of experimentation required to practice this invention is excessive in view of the above discussion of the claim breadth. One need only to prepare variants using routine and often automated procedures, determine whether the degree of homology of the encoding DNA is sufficient for it to hybridize to DNA that encodes the specified regions of SEQ ID NO:2 or SEQ ID NO:13 under the recited conditions, and determine its IL-1 binding characteristics using known binding methodologies or those described in Example 5 of the present specification. All methodologies for performing such tasks are routine and well known in the art and/or disclosed in the present specification and require no inventive effort or thought.

Appellants further argue (Brief, page 10) that "the [e]xaminer [has not] backed up his own assertions with acceptable evidence and reasoning that refutes [a]ppellants showing that methods for preparing variant DNA and polypeptides and methods for testing the variant molecules are within the ordinary skill of those in this art." We agree. It is the examiner who bears the initial burden of providing reasons why a supporting disclosure does not enable a claim. In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). In this case, the rejection under 35 U.S.C. §112, first paragraph, is more of a series of conclusions by the examiner than a fact-based, reasoned explanation as to why a person skilled in the art would not be able to make and use the claimed invention throughout its scope without undue experimentation.

Here, the examiner did not perform the fact-finding needed in order to reach a proper conclusion that it would require undue experimentation, to practice the full scope of appellants' claimed invention. The enablement requirement of 35 U.S.C. or § 112, first paragraph, requires that the patent specification enable "those skilled in the art to make and use the full scope of the claimed invention without 'undue experimentation.'" Genentech, Inc. v. Novo Nordisk. A/S, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997)(quoting In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether making or using the invention would have required undue experimentation, and thus whether the disclosure is enabling, is a legal conclusion based on several underlying factual inquiries. See In re Wands, 858 F.2d 731, 735, 736-37, 8 USPQ2d 1400, 1402, 1404 (Fed. Cir. 1988). As

set forth in Wands, the factors to be considered in determining whether a claimed invention is enabled throughout its scope without undue experimentation include the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

We note that in response to appellants' arguments, the examiner attempts (Answer, pages 8-11) to "shoehorn" his unsupported conclusions into a Wands analysis. However, in the absence of a factual basis to support the examiner's conclusions, the examiner has not sustained his initial burden of establishing a prima facie case of non-enablement. In this regard, we recommend that the examiner review Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 52 USPQ2d 1129 (Fed. Cir. 1999). Therein, the court provided a model analysis of enablement issues and illustrated the type of fact finding which is needed before one is in a proper position to determine whether a given claim is enabled or non-enabled.

The examiner appears to be unduly concerned that the claims include inoperative species. As set forth in Atlas Powder Co. v. E.I. DuPont De Nemours & Co., 750 F.2d 1569, 1576-77, 224 USPQ 409, 414 (Fed. Cir. 1984):

> Even if some of the claimed combinations were inoperative, the claims are not necessarily invalid. "It is not a function of the claims to specifically exclude ... possible inoperative substances ...." In re Dinh-Nguyen, 492 F.2d 856, 859-59, 181 USPQ 46, 48 (CCPA 1974)(emphasis omitted). Accord, In re Geerdes, 491 F.2d 1260, 1265, 180 USPQ 789, 793 (CCPA 1974**);** In re Anderson, 471 F.2d 1237, 1242, 176 USPQ 331, 334-35 (CCPA 1971). Of course, if the number

> of inoperative combinations becomes significant, and in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention, the claims might indeed be invalid. See, e.g., In re Cook, 439 F.2d 730, 735, 169 USPQ 298, 302 (CCPA 1971).

However, on this record, the examiner has not provided the evidence necessary to demonstrate that one of ordinary skill in the art would be forced to experiment unduly n order to practice the claimed invention.

Furthermore, it appears that events may have overtaken this ground of rejection. In this regard, we direct the examiner's attention to United States Patent No. 5,350,683 ('683) issued September 27, 1994. The instant application is a continuation of the Sims patent, which is a divisional of the '683 patent.

We direct the examiner's attention to claim 1 of the '683 patent:

1. An isolated DNA selected from the group consisting of:
(a) a cDNA clone having a nucleotide sequence encoding an amino acid sequence of amino acids 1 through 385 of SEQ ID NO.:2;
(b) a DNA capable of hybridization to a clone of (a) under moderately stringent conditions and which encodes a biologically active type II IL-1R molecule; and
(c) a DNA having a sequence which is degenerate as a result of the genetic code to a DNA as defined in (a) or (b) above and which encodes biologically active type II IL-1R molecules.

Part "(b)" of this claim is drawn to a DNA that encodes a biologically active type II IL-1R molecule and is capable of hybridization under moderately stringent conditions to a cDNA clone having a nucleotide sequence encoding an amino acid sequence of amino acids 1 through 385 of SEQ ID NO.:2. We note the similarity of this DNA claim to appealed claim 16 drawn, in part, to an isolated and purified Type II IL-1 receptor that binds IL-1 and is encoded by a DNA that hybridizes under moderately stringent conditions with a DNA selected from the

group consisting of: (a) a DNA encoding a Type II IL-1R having an amino acid sequence as set forth in SEQ ID NO.:2, having an amino terminus at amino acid 1, and a carboxy terminus selected from the group consisting of an amino acid between amino acids 330 and 385, inclusive, of SEQ ID NO.:2.

The record is silent with regard to what effect if any the claims of the '683 patent would have with regard to the issue before us under 35 U.S.C. § 112, first paragraph. It appears that the instant claims are drawn at least in part to the receptor protein encoded by the DNA set forth in claim 1 of the '683 patent. To that extent, the examiner's instant rejection of the claims under 35 U.S.C. § 112, first paragraph, appears to be inconsistent with the determination that claim 1 of the '683 patent is patentable.

For the reasons set forth above, we vacate the examiner's rejection of claims 16 and 23-25 under 35 U.S.C. § 112, first paragraph. In the event of continued prosecution, the examiner should take a step back and reevaluate whether the information set forth in the specification in conjunction with the relevant prior art, including the '683 patent, enables one to make and use the claimed invention throughout it scope without undue experimentation. If the examiner finds that a rejection is necessary, the examiner should issue an appropriate Office action setting forth such a rejection, using the proper legal standards and clearly setting for the facts relied upon in support of such a rejection.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

William F. Smith Administrative Patent Judge	))))) BOARD OF PATENT
Donald E. Adams Administrative Patent Judge	)) APPEALS AND)) INTERFERENCES
Demetra J. Mills Administrative Patent Judge	))

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